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Bradford R.L. Price, Esq.
Baxter International Inc.
RLP-30
Route 120 and Wilson Road
Round Lake, IL 60073

EXAMINER

TOMASZEWSKI, MICHAEL

ART UNIT PAPER NUMBER

3626

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/864,888	Applicant(s) NG ET AL.	
	Examiner Mike Tomaszewski	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-143 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-143 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>26 August 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice To Applicant

1. This communication is in response to the application filed on 24 May 2001. Claims 49-143 are pending. The IDS statements filed on 26 August 2004, 8 March 2004, 11 August 2003, and 17 January 2003 have been entered and considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 85 and 92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claim 85 is identical to Claim 82 and therefore, is rejected.

(B) Claim 92 is identical to Claim 91 and therefore, is rejected.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 49-143 are rejected under 35 U.S.C. 102(e) as being anticipated by Fletcher-Haynes et al. (US 2001/0034614; hereinafter Fletcher-Haynes).

(A) As per Claim 49, Fletcher-Haynes discloses a system for managing a procedure in a blood component collection facility, the system comprising:

(a) a blood component donor identifier corresponding to a blood component donor (Fletcher-Haynes: par. [0167]);

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- (b) an operator identifier corresponding to a blood component collection instrument operator (Fletcher-Haynes: par. [0079] and Fig. 6D);
- (c) a blood component collection instrument for collecting a blood component from the blood component donor (Fletcher-Haynes: par. [0056]);
- (d) a system computer being operably connected to the blood component collection instrument, the system computer running a blood component collection application defining at least one step of a blood component collection process (Fletcher-Haynes: par. [0057] and Fig. 1A); and
- (e) an interface having a reader and being operably connected to the system computer for receiving the blood component donor identifier and the operator identifier and transmitting the operator identifier to the system computer proximate the performance of the at least one step of the blood component collection process (Fletcher-Haynes: par. [0057], [0059], [0071], and [0079]; Fig. 6D).

(B) As per Claim 50, Fletcher-Haynes discloses the system of Claim 49, wherein blood component collection application comprises at least one code segment, the at least one code segment selected from a group consisting of a blood component collection initialization code segment, an arm-prep code segment, a remove-blood component code segment, and a disconnect-blood-component-donor code segment (Fletcher-Haynes: par. [0012] and [0069]).

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Examiner has noted insofar as Claim 50 recites "at least one code segment selected from a group consisting of a blood component collection initialization code segment, an arm-prep code segment, a remove-blood component code segment, and a disconnect-blood-component-donor code segment," a blood component collection initialization code segment has been recited.

(C) As per Claim 51, Fletcher-Haynes discloses the system of Claim 49, wherein the blood collection component application associates the blood component donor identifier with the operator identifier (Fletcher-Haynes: par. [0012], [0179] and [0180]; Fig. 6D and 6E).

(D) As per Claim 52, Fletcher-Haynes discloses the system of Claim 51, wherein the reader receives separate input of the blood component donor identifier and the operator identifier from a location proximate the blood component collection instrument (Fletcher-Haynes: par. [0059], [0071] and [0079]).

(E) As per Claim 53, Fletcher-Haynes discloses the system of Claim 51, wherein the reader receives separate input of the blood component donor identifier and the operator identifier proximate in time one from the other and prior to blood component collection (Fletcher-Haynes: par. [0059], [0071] and [0079]).

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(F) As per Claim 54, Fletcher-Haynes discloses the system of Claim 49, wherein the operator identifier is transmitted to the system computer after the performance of the at least one step of the blood component collection process (Fletcher-Haynes: par. [0179]; Fig. 6A-6J).

(G) As per Claim 55, Fletcher-Haynes discloses the system of Claim 49, further comprising a second interface operably connected to the system computer, the second interface for providing access to the data related to the blood component collection process (Fletcher-Haynes: par. [0027] and [0030]).

(H) As per Claim 56, Fletcher-Haynes discloses the system of Claim 55, wherein the second interface provides access to at least a portion of the data related to the blood component collection process, the data being received by the second interface in response to a request received by the system computer (Fletcher-Haynes: par. [0027] and [0030]).

(I) As per Claim 57, Fletcher-Haynes discloses the system of Claim 55, wherein the second interface provides access to remote blood component collection facility data (Fletcher-Haynes: par. [0012], [0030], and [0033]).

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(J) As per Claim 58, Fletcher-Haynes discloses the system of Claim 55, wherein the second interface provides access to performance statistics for the blood component collection process (Fletcher-Haynes: par. [0030], [0144], [0155], and [0157]).

(K) As per Claim 59, Fletcher-Haynes discloses the system of Claim 55, wherein the second interface provides access to a record of an operator's interaction with the blood component collection facility, the interaction of the operator with the blood component collection facility having been concomitantly logged into the memory for the blood component collection process by the operator via the interface (Fletcher-Haynes: par. [0019], [0030], [0027], and [0179]).

(L) As per Claim 60, Fletcher-Haynes discloses the system of Claim 55, wherein the second interface provides access to information related to the donor (Fletcher-Haynes: par. [0027] and [0030]).

(M) As per Claim 61, Fletcher-Haynes discloses the system of Claim 55, wherein the second interface provides access to information related to the blood component collection instrument (Fletcher-Haynes: par. [0027] and [0030]).

(O) As per Claim 62, Fletcher-Haynes discloses the system of Claim 55, wherein the second interface provides access to quality assurance statistics of the blood component collection facility (Fletcher-Haynes: par. [0013], [0018], [0027] and [0030]).

(P) As per Claim 63, Fletcher-Haynes discloses the system of Claim 55, further comprising an operator identifier wherein the operator utilizes the interface to transmit the operator identifier and the blood component collection kit identifier to the system computer (Fletcher-Haynes: par. [0022], [0057], [0125] and [0179]; Fig. 6A-6D).

(Q) As per Claim 64, Fletcher-Haynes discloses the system of Claim 49, further comprising a blood component collection kit for connection to the blood component collection instrument, the kit having a blood component collection kit identifier (Fletcher-Haynes: par. [0022] and [0125]; Fig. 6A-6D).

(R) As per Claim 65, Fletcher-Haynes discloses the system of Claim 49, wherein the blood component collection process further comprises a blood component collection instrument set-up procedure (Fletcher-Haynes: par. [0072] and [0119]; Fig. 3A-3F).

(S) As per Claim 66, Fletcher-Haynes discloses the system of Claim 49, wherein the reader comprises a touch pad for entering the request for information logged into the system computer (Fletcher-Haynes: par. [0057]).

Examiner has noted insofar as Claim 66 recites "at least one of a touch pad, a keypad, an optical scanner and a magnetic scanner," a touch pad (i.e., touch screen) has been recited.

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(T) As per Claim 67, Fletcher-Haynes discloses the system of Claim 49, further comprising a report generated by the blood component collection application and displayed via the interface, wherein the report provides blood component collection facility information associated with the donor (Fletcher-Haynes: par. [0012], [0026], [0030] and [0075]).

(U) As per Claim 68, Fletcher-Haynes discloses the system of Claim 49 comprising a report generated by the blood component collection application and displayed via the interface, wherein the report for provides blood component collection facility information associated to the blood component collection kit (Fletcher-Haynes: par. [0012], [0026], [0030], [0022], [0075], [0125]; Fig. 6A-6D).

(V) As per Claim 69, Fletcher-Haynes discloses the system of Claim 49, further comprising a remote server operably connected to the system computer via a communication network, wherein the remote server monitors and tracks a remote blood collection facility (Fletcher-Haynes: par. [0012]; Fig. 1A-1D).

(W) As per Claim 70, Fletcher-Haynes discloses the system of Claim 69, wherein a second interface provides access to the remote server through a browser within the second interface (Fletcher-Haynes: par. [0012], [0030] and [0194]).

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(X) As per Claim 71, Fletcher-Haynes discloses the system of Claim 69, wherein a second interface provides access to data received by the system computer from the remote server (Fletcher-Haynes: par. [0012] and [0030]).

(Y) As per Claim 72, Fletcher-Haynes discloses the system of Claim 50, wherein blood-component-collection-initialization code segment requests a blood component instrument identifier (Fletcher-Haynes: par. [0012], [0069] and [0159]; Fig. 5A).

(Z) As per Claim 73, Fletcher-Haynes discloses the system of Claim 72, wherein the blood-component-collection-initialization code segment further requests a blood component collection process identifier (Fletcher-Haynes: par. [0012], [0019], [0069] and Fig. 6E).

(AA) As per Claim 74, Fletcher-Haynes discloses the system of Claim 73, wherein the blood-component-collection-initialization code segment further requests the donor identifier (Fletcher-Haynes: par. [0012], [0069], and [0167]; Fig. 6A).

(BB) As per Claim 75, Fletcher-Haynes discloses the system of Claim 74, wherein the blood-component-collection-initialization code segment further requests the operator identifier (Fletcher-Haynes: par. [0012], [0069], and [0079]; Fig. 6D).

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(CC) As per Claim 76, Fletcher-Haynes discloses the system of Claim 50, wherein the arm-prep code segment further requests an anatomical location on the donor for drawing the blood component (Fletcher-Haynes: par. [0019], [0086], [0094], [0157], [0160] and [0166] and [0182]).

Examiner notes also that Fletcher-Haynes teaches the use of dialog boxes to record comments (e.g., location on donor where the blood component was or is to be drawn from) regarding all phases of the blood collection process.

(DD) Claims 77-86 substantially repeat the same limitations of Claims 72-75 and therefore, are rejected for the same reasons given for those claims.

(EE) As per Claim 87, Fletcher-Haynes discloses the system of Claim 86, wherein the remove-blood-component code segment further requests confirmation of a calculated amount of blood component to be removed and an actual amount of blood component removed (Fletcher-Haynes: par. [0177], [0184] and [0185]; Fig. 3C-6M).

(FF) As per Claim 88, Fletcher-Haynes discloses the system of Claim 87, wherein the remove-blood-component code segment further requests a reason for a difference between the calculated amount of blood component to be removed and the actual amount of blood component removed (Fletcher-Haynes: par. [0018], [0075], [0086], [0094], [0157], [0160] and [0166] and [0182]).

Examiner notes that Fletcher-Haynes teaches the use of dialog boxes to record comments (e.g., discrepancies between calculated and actual amounts of blood collected) regarding various phases of the blood collection process.

(GG) As per Claim 89, Fletcher-Haynes discloses the system of Claim 88, wherein the disconnect-blood-component-donor code segment further requests the operator identifier of the operator administering the disconnect-blood-component-donor procedure (Fletcher-Haynes: par. [0012], [0069], [0079], and [0191]; Fig. 6D).

(HH) As per Claim 90, Fletcher-Haynes discloses the system of Claim 50, wherein the disconnect-blood-component-donor code segment further requests a reaction of the blood donor during the blood component collection process (Fletcher-Haynes: par. [0019], [0086], [0094], [0157], [0160] and [0166] and [0182]).

Examiner notes that Fletcher-Haynes teaches the use of dialog boxes to record comments (e.g., donor reactions during the blood collection process) regarding various phases of the blood collection process.

(II) As per Claim 91, Fletcher-Haynes discloses the system of Claim 49, further comprising an alarm generated by the blood component collection application and displayed via the interface for alerting the operator of a condition affecting the blood component collection process (Fletcher-Haynes: par. [0019], [0155], [0158], [0159], [0163], and [0182]).

(JJ) Claim 92 repeats the same limitations of Claim 91 and is therefore, rejected for the same reasons given for Claim 91.

(KK) As per Claim 93, Fletcher-Haynes discloses the system of Claim 49, wherein blood component collection application comprises at least one code segment for receiving data, the data selected from instrument set-up data (Fletcher-Haynes: par. [0014] and [0072]; Fig. 3A-3F).

Examiner has noted insofar as Claim 93 recites "at least one code segment for receiving data, the data selected from a group consisting of clearing instrument alarm data, clearing instrument alert data, instrument set-up data, soft good data, program procedure data, arm-prep data, venipuncture data, remove plasma data, disconnect data, saline data, donor reaction data, re-sync data, move donor data, procedure termination data, change component data, maintenance data, field service data, out-of-service data, and in-service data," instrument set-up data has been recited.

(LL) Claims 94 and 95 substantially repeat the same limitations as Claims 75 and 72, respectively and therefore, are rejected for the same reasons given for those claims.

(MM) As per Claim 96, Fletcher-Haynes discloses the system of Claim 93, wherein the at least one code segment associates the operator identifier with the data (Fletcher-Haynes: par. [0018] and [0179]; Fig. 6A-6J).

(NN) As per Claim 97, Fletcher-Haynes discloses the system of Claim 93, wherein the at least one code segment associates a blood component collection instrument identifier with the data (Fletcher-Haynes: par. [0159]; 6A-6J).

(OO) Claim 98 differs from system Claim 49 by reciting " a computer readable medium having a computer program code stored thereon" within its preamble. As per these elements, Fletcher-Haynes' blood processing information management system includes computers, server systems, software, databases and display monitors (Fletcher-Haynes: par. [0012], [0014], [0038], [0059]; Fig. 1A-1D). As such, it is readily apparent that the Fletcher-Haynes system is controlled by a computer program stored upon a computer-readable medium.

The remainder of Claim 98 repeats the same limitations of system Claim 49 and is therefore, rejected for the same reasons given for Claim 49, and incorporated herein.

(PP) Claim 143 differs from system Claim 49 by excluding hardware elements, namely, a computer, a blood collection instrument, an application, and an interface. As such, Claim 143 is rejected for the same reasons given for Claim 49.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied art teaches a blood plasma collection system (5,132,026); a modular health-care information management system utilizing reusable software objects (5,995,937 and 6,314,556); a method and system for anonymously testing for a human malady (5,978,466); and a method of configuring blood circuit for medical application and configuration apparatus therefore (US 2002/0013715).

The cited but not applied prior art also includes non-patent literature articles by Gary Forger ("How An AS/RS and Two AGV Systems Saved the Day at Terumo" Dec. 1989. Modern Materials Handling. Vol. 44, Iss. 14. pg. 44.) and John Gorman ("Hemocare Adds LifeTrak to Its Blood Bank Family Windows-Based Blood Donor Software Now Available to Blood Bank Industry" Nov. 3, 1999. PR Newswire. pg. 1.).


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MT

 9.20.05


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER